

K 960394

510(k) SUMMARY
SureSkin® STANDARD Hydrocolloid Wound Dressing

1. DATE PREPARED

January 25, 1996

2. SUBMITTER

Euromed A/S
Borgergade 6
DK-1300 Copenhagen
Denmark

3. CONTACT

Mr. Carsten Fredsbo
General Manager
Phone: 011-45-3316-3040

4. DEVICE NAME

SureSkin® STANDARD Hydrocolloid Wound Dressing

5. DEVICE CLASSIFICATION

Wound Dressings have not been finally classified by FDA.
[Proposed Class I (21 CFR 878.4022)]
Product Code: 79 MGP

6. DEVICE DESCRIPTION AND COMPARISON TO PREDICATE PRODUCTS

The SureSkin® STANDARD Hydrocolloid Wound Dressing manufactured by Euromed A/S is a wound dressing indicated for the management of light to heavy exudating pressure

sores and leg ulcers. It is composed of a hydrocolloid material which is in contact with the wound, and an occlusive polyurethane backing. The dressing is similar in design, function, materials, and intended use to other hydrocolloid/occlusive dressings currently in commercial distribution, e.g., DuoDerm Dressing marketed by Convatec.

Determination of substantial equivalence for this product was based on descriptive information about the design, materials, and intended use of the device. Biocompatibility testing was performed on the device material in conformance with Tripartite and ISO 10993 recommendations. Results of all biocompatibility tests demonstrated that the device is suitable for its intended use.